66307-358

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	PATENT
	)	
William CHARMAN *et al.*	)	GROUP:
	)	
Serial No.: (PCT/GB2004/003329)	)	EXAMINER:
	)	
Filed: (30 July 2004)	)	CUSTOMER NO.: 25269
	)	
IMPROVED DRUG DELIVERY SYSTEM	)	CONFIRMATION NO.

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

January 27, 2006

Sir:

The inventors enclose copies of the patent documents listed in the International Search Report, dated 24 February 2005.

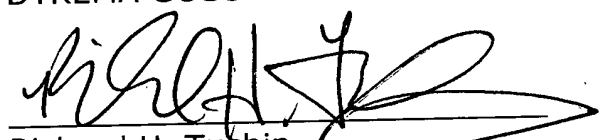
Claim 1 of the present application is concerned with an oral drug delivery system which comprises a continuous hydrophilic phase, a pharmaceutically acceptable oil which forms a discontinuous phase and having a drug dissolved or dispersed therein, and a surfactant to enable the formation of a stable biliquid foam. In particular, the drug delivery system of claim 1 has a poorly water-soluble drug dissolved in the pharmaceutically acceptable oil, wherein a "poorly water-soluble drug" is defined as a drug which dissolves in water in an amount of less than 1% by weight. The poorly water-soluble drug of the present invention is present in the oil discontinuous phase, and remains in that phase. The

drug cannot escape into the continuous hydrophilic phase since it is not soluble in that phase.

In contrast to this, U.S. Patent No. 4,999,198 to Barnett et al. discloses a polyaphron composition having a continuous phase and a disperse phase in which the drug is carried in the disperse phase (see the Abstract). However, the drug must be water-soluble. This is because the invention of Barnett et al. is to allow the drug to be transferred easily into an aqueous medium (see column 1, lines 46 to 50 and claim 1). It is submitted that the present invention is novel over Barnett et al. not least because the generic reference to drugs in Barnett et al., and the specific disclosure of scopolamine, are for drugs which are water-soluble, otherwise they could not be transferred into the aqueous medium. This is unlike claim 1 of the present application which requires the drug to be poorly water-soluble as indicated above.

Respectfully submitted,

DYKEMA GOSSETT PLLC

By: 

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INFORMATION DISCLOSURE STATEMENT **Form PTO-1449** **(Use several sheets if necessary)**	ATTY. DOCKET NO. 66307-358	SERIAL NO. (PCT/GB2004/003329) 10/566209
	APPLICANT William CHARMAN *et al.*	
	FILING DATE (30 July 2004)	GROUP

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
		4,999,198	3/1991	Barnett *et al.*			
		4,486,333	12/1984	Sebba			

U.S. PATENT APPLICATION PUBLICATIONS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
		97/32559	9/1997	WIPO				
		01/62214	8/2001	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

EXAMINER	DATE CONSIDERED

Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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